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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,251	01/04/2002	Kazuya Takenouchi	Q67009	4355

• 7590 04/27/2004

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Sabiha N. Qazi

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 45-65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 45-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

Non-Final Office Action

Acknowledgement is made of the response filed on 11/21/03. Amendments are entered. Claims 45-65 are pending. No claim is allowed.

Presently claimed invention is drawn to vitamin D compounds of formula (I), compositions and their method for treating an inflammatory respiratory disease.

Double Patenting rejection over 10/325217 is maintained for the same reason as set forth in our previous office action; other rejections are withdrawn because Terminal disclaimer has been filed. Rejection of claims 66-69 is moot because claims are canceled.

Examiner respectfully disagrees with the arguments that double patenting rejection is moot over claims of 10/035,217 because claims 66-69 are canceled. Claims are drawn to method of treating inflammatory respiratory disease, which has been allowed recently in 10/035,217. Claims of the application are not available to the Examiner at this time. A telephonic call was made to Attorney Jennifer Hayes on 4/21/04 to make a request for copy of claims of 10/035,217. Unfortunately Ms. Hayes was not available.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claim 45-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

3. What is intended by the term "derivative" in this claim? What is the meaning of "composed of" in claim 61?
4. It is unclear what is intended by "already shown in the formula" in claims (see for example claim 45, 55 and other claims?
5. Claim 51-60 is improperly dependent on claim 46 (there is no formula (1).
6. Claims 48-50 is improperly dependent on claims 45, 46 and 47.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 66-69 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims are rejected because they are drawn to method of treating respiratory diseases selected from acute upper airway infection, Chronic sinusitis, allergic rhinitis, respiratory distress syndrome, cystic fibrosis, common cold, pulmonary fibrosis as listed in claims 62-65 and these are not enabled in specification.

There is nothing in the disclosure where one skilled in the art would be able to treat such diseases by the wide range of the compounds of formula (I) without undue experimentation.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation.

The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)).

Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971)).

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988)).

Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of

experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:

The nature of the invention:

Presently claimed invention is drawn to methods of treating several respiratory diseases by a wide variety of vitamin D compounds covered by formula (I).

The state of the prior art and the predictability or lack thereof in the art:

There is a lack of predictability in the pharmaceutical art. In this case treatment of respiratory disease is selected from acute upper airway infection, Chronic sinusitis, allergic rhinitis, respiratory distress syndrome, cystic fibrosis, pulmonary fibrosis.

The amount of direction or guidance present and the presence or absence of working examples:

Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991).

No example is drawn to for the treatment of common cold or the diseases listed in claims.

One skilled in the art would have no idea how to practice the invention.

The breadth of the claims and the quantity of experimentation needed:

Since the nature of methods as claimed is unpredictable and there is lack of guidance present in the specification, one skilled in the art would have to go through undue experimentation to make and use the presently claimed invention.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi whose telephone number is (571) 272-

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sabiha N. Qazi
Primary Examiner
Art Unit 1616

4/23/04